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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,507	11/07/2003	Jacques Degelaen	2003_1624	8535
513	7590	09/22/2006	EXAMINER	
WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			NGUYEN, BAO THUY L	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/702,507

Applicant(s)

DEGELAEN ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/297,196.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The preliminary amendments dated 07 November 2003 and 18 December 2003 have been received.
2. Claims 1-23 have been cancelled. Claims 24-40 have been added and are pending.

Claim Rejections - 35 USC § 112

3. Claims 24-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is vague with respect to the location of the detection reagent. It is unclear if the detection reagent is located on the solid support or if it is in a separate container.

Claim 24 also recite an optional component, therefore, it has not been given patentable weight.

Claim 32 is confusing because it recites specific type of analytes, however, it is unclear how "analyte" can be packaged with a test kit.

Claims 36-39 are vague because they appear to be method steps and thus do not further limit the assay kit claims from which they depend.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 24-34 and 36-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markovsky et al (US 6,319,466) in view of Joris (FEMS Microbiology Letters. Vol. 70. No. 1. 15 June 1990. Pages 107-113).

Markovsky discloses a device comprising a labeled receptor positioned within or proximate to a membrane. The membrane comprises a test zone having an analyte conjugate immobilized thereto to bind unbound receptor to form a first analyte conjugate receptor complex. The membrane further comprising a control zone

including a binder immobilized thereto. See column 1, lines 52-67. Markovsky teaches that the receptor may bind a family of analytes which have similar structural binding sites. Markovsky also discloses a sample absorbing and a mobile-phase support zone acting as a filter for somatic cells. See column 9, lines 7-14. The mobile-phase support zone is preferably Porex® pad or Porex® Lateral Flow Media. See column 10, lines 25-29. The device is configured to detect analytes such as beta lactams antibiotics in milk samples. See column 5, lines 11-20. The entire device is provided in a blister package including a removable seal strip at one end for application of the sample. See column 4, lines 8-20. Markovsky teaches that competitive assays for beta-lactams in milk sample can be done in 2 to 15 minutes. See column 3, lines 26-32. Markovsky teaches that test kits for detecting beta-lactams in biological fluids are well known in the art. See column 1.

Markovsky differs from the invention in failing to teach receptors obtained from *Bacillus lichenformis* as the labeled reagent.

Joris et al discloses BLAR and BLAR-CTD involved in β -lactamase inducibility in *Bacillus lichenformis*.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the receptors taught by Joris in the device of Markovsky because Markovsky teaches that their device can be modified for the detection of a variety of analytes using appropriate reagents. See column 13, lines 23-39. Since Joris discloses that receptors of as BLAR and BLAR-CTD are readily available are and well

known in the art as having β -lactamase activity, a skilled artisan would have had a reasonable expectation of success in choosing the appropriate reagents for a particular analyte as taught by Markovsky.

Even though Markovsky does not specifically teaches that the mobile-phase support zone (i.e. purification membrane) retains leukocytes, Markovsky teaches that this zone is capable of filtering somatic cells, therefore, a skilled artisan would have had a reasonable expectation of success that such a membrane is capable of retaining leukocytes.

6. Claims 25 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markovsky in view of Joris as applied to claim 24 above, and further in view of Pall et al (US 6,074,869).

See the discussion of Markovsky and Joris above. These references differ from the instant invention in failing to specifically disclose the pore size of the purification membrane.

Pall, however, teaches membranes for filtering biological samples, including leukocytes and milk sample. See column 6, lines 32-62. Pall teaches that their membrane is non-woven web and having an average pore size of 3 to 8 μ m. See column 8, lines 54-60.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the purification membrane taught by Pall in the device of Markovsky as modified by Joris because such a membrane is well known in


the art and provides the advantage of a substantially uniform porous medium that can separate large somatic cells from a biological sample.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


BAO-THUY L. NGUYEN
PRIMARY EXAMINER
9/14/06